Arizona Medical Board

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DRAFT MINUTES FOR TELECONFERENCE OF SUBCOMMITTEE ON OFFICE BASED SURGERY Held at 5:00 p.m. on Tuesday, May 29, 2007 9545 E. Doubletree Ranch Road · Scottsdale, Arizona

Subcommittee Members
William R. Martin, III, M.D., Chair
Ram R. Krishna, M.D.
Douglas D. Lee, M.D.

CALL TO ORDER
The meeting was called to order at 5:00 p.m.

ROLL CALL
The following Subcommittee members were present William R. Martin, III, M.D., Ram R. Krishna, M.D., and Douglas D. Lee, M.D.

CALL TO PUBLIC
There was no one to speak to call to public.

NON-TIME SPECIFIC ITEMS

Approval of Minutes
August 10, 2005 Meeting Minutes

MOTION: Ram R. Krishna, M.D. moved to approve the August 10, 2005 Meeting Minutes.
SECONDED: Douglas D. Lee, M.D.

Office Based Surgery Rule Discussion
Timothy C. Miller, J.D. informed the Subcommittee that Staff received numerous comments regarding the proposed Office Based Surgery Rules during the oral proceeding. Staff considered each of the comments received and evaluated whether substantive changes to the Rules were needed.

The Subcommittee reviewed suggestions on the rules and made the following comments:

R4-16-101(5): The Board received comments suggesting that the definition of "deep sedation" be changed by adding "the ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained." The Subcommittee found this unnecessary because the definition already states that ventilatory function may be impaired. The Subcommittee also agreed "cardiovascular function is usually maintained" does not need to be added because if a patient is unable to maintain cardiovascular function, the patient has been given general anesthesia which is prohibited.

R4-16-101(6): The Board received a comment that the definition of "discharge" be modified to incorporate the concept of the release from the office of a patient who has met the criteria for recovery from the surgical procedure. The Subcommittee agreed not to change this because regulatory language should not be included in a definition. The standard of care requires that a physician determine that a patient meet discharge criteria for recovery from the surgical procedure before discharge. An analysis of A.R.S. §32-1401(27)(q) and (ll) will allow the Board to determine if there is a violation or not.

R4-16-101(9): The Board received one comment that suggested changing the definition of "emergency drug" to incorporate the concept of drug administered in response to an emergency. The Subcommittee agreed the meaning of the rule is not changed by adding "in response to" an emergency, thus there is no reason to make this change.

R4-16-101(10): The Board received one comment suggesting the definition of "general anesthesia" contain the phrase "that intervention is often required to maintain the patient's airway." The Subcommittee agreed the definition describes the state of the patient not the actions that might need to be taken by the physician. The recommendation could be considered to be a regulatory provision, which should not be included in a definition.

R4-16-101(11): The Board received two comments stating the definition of "health care professional" is too vague and could be interpreted to allow RNs, PAs, and others to administer sedation, which would be outside their scope of practice and suggested that the rules state that administering sedation must be within the health care provider's scope of practice. The Subcommittee agreed since the administrative boards that license the health care professionals require that the health care professionals practice within their scope of practice it is unnecessary for the Board to also define the scope of practice of these individuals. Additionally, the Rule, as written, does not authorize anyone to do something outside their scope of practice.

R4-16-101(12): The Board received one comment that the definition of "informed consent" should be expanded to cover the entire procedure and suggests adding "the purpose, its alternatives, and risks and benefits." The Subcommittee agreed the definition already contains these requirements. The Subcommittee also agreed R4-16-702(A)(4) makes it clear that the physician must obtain informed consent before performing office-based surgery using sedation that authorizes the office-based surgery and also authorizes the office-based surgery to be performed in the physician's office.

R4-16-101(14): The Board received two comments stating the definition of "minimal sedation" was too broad and would apply to all drugs with a sedative effect. The Subcommittee agreed the changing of the definition would be unnecessary since the rules regulate the administration of sedation for the purposes of performing surgery and if no surgery is involved during a medical procedure the rules do not apply. The Subcommittee also agreed that if a drug is not used to sedate a patient for the purpose of surgery, the rules do not apply.

The Board received two comments requesting that the statutory definition of "office-based surgery" be narrowed in the rules. The Subcommittee was in agreement that the Board cannot change a statutory definition by rule.

The Board received one comment requesting that the rules prohibit colonoscopies from being performed in a doctor's office. The Subcommittee agreed the purpose of the rules is not to restrict or authorize the surgical procedures that may be performed by physicians, but to provide standards for regulating surgical procedures that are being performed by physicians in offices. This allows the Board to look at the standard of care and the procedure to determine if it can be safely performed in an office setting.

The Board received one comment requesting that the rules exempt hair restoration and similar procedures from the requirements in the rules. The Subcommittee agreed that in order to protect the health and safety of patients the rules should apply to these procedures if the procedures fall within the definition of office-based surgery using sedation.

R4-16-603(20): The Board received one comment that suggested adding a penalty for using general anesthesia in an office-based setting. The Subcommittee agreed the Board already has authority to discipline a physician for using general anesthesia in an unlicensed facility in A.R.S. § 32-1401(A) (27) and does not need to add this provision to the rule. Additionally, Mr. Miller noted that the Arizona Department of Health Services (ADHS), as regulators of facilities, would have the authority to penalize the facility.

R4-16-702(A): The Board received two comments requesting that the Board clarify in the rules that the rules do not apply to any facility licensed by ADHS. The Subcommittee agreed the rules only apply to physicians who are practicing in offices that are exempt from ADHS jurisdiction pursuant to A.R.S. § 36-402(A) (3), therefore it is unnecessary to make this change.

R4-16-702(A)(2): The Board received one comment stating that the rules allow inadequately trained individuals to administer deep sedation. The Subcommittee was in agreement that the rules require the staff member or health care professional have adequate training to perform any tasks involving office-based surgery and if applicable, is certified or licensed. The Subcommittee agreed that if Arizona law requires that a person be licensed to perform that particular procedure, then these rules would not allow an unlicensed or non-certified person to perform the procedure.

R4-16-704(A)(4)(b): The Board received one comment that a list of facilities authorized to perform office-based surgeries using sedation be maintained by the Board. The Subcommittee agreed it is not the intent of these rules to license or

approve facilities where office-based surgeries using sedation are performed, but to regulate the physicians who perform office-based surgeries using sedation.

R4-16-703: The Board received several comments requesting that the rules require the health care professionals have the scope to administer sedation and have training and ability to deal with general anesthesia if the health care professional plans to use deep sedation. The Subcommittee agreed if the law requires certification or licensure to perform a procedure, then the person performing the procedures under these rules must be licensed or certified.

R4-16-703: The Board received one comment requesting that surgeons only perform surgeries that they have privileges to perform in a hospital. The Subcommittee agreed that requiring hospital privileges would allow hospitals to determine who can perform office-based surgeries. Douglas D. Lee, M.D. wondered how the Board will hold a physician responsible for performing procedures he is not qualified to do. William R. Martin, III, M.D. responded by stating the Board would have to expect physicians to practice within their scope and ability or the Board may take action against the licensee. Mr. Miller added that the Subcommittee previously agreed not to codify the standard of care as it is constantly changing. R4-16-703 states that a physician must ensure the procedure can be safely performed in an office setting. Ram R. Krishna, M.D. stated the Board's purpose is to set parameters. Dr. Martin added that requiring hospital privileges would affect a physician's ability to practice. A hospital's reasons for granting or not granting privileges may not always be altruistic. Christine Cassetta, Board Legal Counsel, stated by adopting office-based surgery statutes and rules the Board is taking a proactive role.

R4-16-703(A)(2): The Board received three comments requesting that the rule be changed from stating "the office-based surgery using sedation is of duration and degree of complexity that allows a patient to be discharged from the physician's office within 24 hours" to situations where the patient does not stay overnight. The Subcommittee agreed if a patient stays overnight, then the office must be licensed by ADHS and therefore these rules would not apply and any procedure that requires greater than 24 hours recovery period is an inpatient procedure and may not be performed in an office.

R4-16-703(B)(1): The Board received one comment stating that "undue risk of complications" was too ambiguous. The Subcommittee agreed that all procedures have a risk of complication and "undue risk of complications" indicates a risk that is more than the usual risks associated with the surgical procedure.

R4-16-703(B)(2): The Board received one comment stating that the rule states a level of predictability that may not be achievable and requests that the rule be changed to "May reasonably be expected to require services at a hospital." The Subcommittee agreed the intent of the rule is to prevent a physician from performing a surgical procedure if the physician knows or should have known the surgical procedure will require a hospital stay and if the physician was to perform a surgical procedure that would require a hospital stay, the physician would not qualify for the exemption in A.R.S. § 36-402(A)(3) and would be required to be licensed as a health care institution. The Subcommittee also agreed it is up to the physician to determine of the patient needs inpatient recovery or a hospital stay.

R4-16-704: The Board received one comment stating that a registered nurse be responsible for monitoring. The Subcommittee agreed the rules require that physicians performing office-based surgery using sedation ensure that all staff is competent to perform assigned tasks and if necessary be licensed or certified. The Subcommittee agreed the Board would have to determine case by case if the physician picked the appropriate person to monitor.

R4-16-704: The Board received one comment stating that the rule should be clarified so it does not appear that the physician who is performing the surgery is also administering the sedation. The Subcommittee agreed it is not the intent of the rule to prohibit the surgeon from administering the sedation and monitoring the patient, if the physician can safely perform the surgical procedure and simultaneously monitor the patient and that that practice is consistent with the community standard of care. Each situation is different and the Board would conduct an analysis of A.R.S. §32-1401(27)(q) and (ll) to determine whether the standard of care was met.

R4-16-704: The Board received one comment requesting that the Board require that the physician ensure that the requirements in R4-16-704 are met rather than requiring the physician to meet the requirements. The Subcommittee agreed the intent of the rule is to require a physician performing office-based surgery using sedation to ensure that the requirements are met. Dr. Lee clarified that physicians would still be responsible for delegated tasks. The Subcommittee concurred.

R4-16-704(1): The Board received two comments stating that pulse oximetry for minimal sedation is not necessary and the requirements for minimal sedation are too high. The Subcommittee agreed this requirement must be met to protect the health and safety of patients. Therefore, no changes will be made to this rule as a result of this comment.

R4-16-704(2)(a): The Board received four comments stating that oxygenation is different than ventilation and the rules should require both. The rules should include a requirement that the physician be required to monitor ventilation by observation, auscultation, capnography or other reliable forms of apnea monitoring. The Subcommittee agreed the Board

make the recommended change to the rule. Dr. Lee recommended having both oxygenation and ventilation included since these are separate issues and need to be monitored. Mr. Miller stated that Staff unintentionally left ventilation out of the Rule. The Subcommittee agreed both should be included.

R4-16-704(2)(c): The Board received three comments stating that temperature monitoring is only necessary if the physician expects temperature fluctuation. Another commenter requested the Board change the rule to read "monitor temperature when clinically significant changes in body temperature are intended, anticipated, or suspected." The Subcommittee agreed the rule provides a physician with the discretion to monitor the temperature of the patient as he or she determines. This discretion includes situations where the surgeon expects clinically significant changes in the body temperature. Therefore, the Board will make no changes to the rule as a result of these comments.

R4-16-704(2)(d): The Board received one comment stating that a surgeon may not be able to supervise staff adequately because the surgeon will be doing other equally important tasks. The Subcommittee agreed the surgeon must supervise a staff member or health care professional as needed by the staff member or health care professional. The Subcommittee also agreed the availability of the surgeon would be based on the scope of practice of the person who is doing the monitoring.

R4-16-705(1): The Board was asked for what time period the physician is required to stay with a patient according to this Rule. The Subcommittee agreed a physician can leave an office when sedation monitoring is completed.

R4-16-705(2): The Board received one comment suggesting the use of the word "discharged" rather than "discontinued." The Subcommittee was in agreement that it is necessary for a physician to be at the physician's office and sufficiently free of other duties until post-sedation monitoring is discontinued. The Subcommittee agreed there is a difference between discharging the patient and stopping monitoring. In some instances the patient may be discharged some time after the post-sedation monitoring is discontinued. It is not always necessary for the physician to remain until discharge.

R4-16-705(3): The Board received three comments that unlicensed persons cannot get certified and that ACLS, BLS, and PALS are not necessary for minimal sedation. The Subcommittee agreed that unlicensed persons cannot be certified. The Board will delete the reference to staff members in subsection (3) and (4).

R4-16-705(4): The Board received one comment suggesting the insertion of the word "currently" before "certified." The Subcommittee was in agreement that the rule language that states "is certified" means the same as currently certified, and therefore no change is necessary.

R4-16-705(5): The Board received one comment suggesting the Board require the physician document that the discharge criteria were met prior to discharge. The Subcommittee was in agreement that the purpose of the rule is to set out documentation requirements, not standard of care requirements and that the information contained in the discharge will be included in a standard of care analysis.

R4-16-706: The Board received two comments stating that the rules should require the physician to have the skills, training, and equipment to rescue a patient from deeper sedation than expected. The Subcommittee was in agreement that this is already stated in the rules. R4-16-703(A)(3) requires that the physician perform only the office-based surgery using sedation that is within the education, training, experience, and skills of the physician, which would include the education, training, experience, and skills to rescue a patient from deeper sedation than expected. The Subcommittee agreed that this is also a matter of the standard of care. Therefore, there will be no changes to the rule as a result of this comment.

The Board received one comment stating that the requirements in R4-16-706 are unnecessary for minimum sedation. The Subcommittee agreed that the rules are necessary to protect the health and safety of patients who are provided with minimal sedation. A.R.S. Title 4, Chapter 13 does not exempt minimal sedation from regulation. The Subcommittee also noted that it is not clear when patients transfer from minimal to moderate sedation. That is why the Rule applies to minimal, moderate and deep sedation.

The Board received one comment that language about endotracheal intubation should be added to the rule. The Subcommittee was in agreement that it is unnecessary to add this requirement because in order for a health care professional or physician to be ALS certified, the health care professional or physician is required to know how to do this.

R4-16-706(A)(1)(a): The Board received one comment stating that the rules should require both the FiO2 and SaO2 monitor because they perform different functions. Dr. Lee agreed with this statement. He said that the FiO2 monitors the equipment's delivery of oxygen, while the SiO2 monitors the oxygen concentration in the patient. An FiO2 monitor is only needed when delivering oxygen in deep sedation settings. The Subcommittee agreed that some surgical procedures do not need to be performed using both types of monitoring. R4-16-703(A)(1) requires that a physician ensure that the office-based

surgery using sedation be safely performed with the equipment at the physician's office. The Subcommittee agreed to strike FiO2 because it is not used in office-based settings, with a few exceptions.

R4-16-706(A)(1)(a): The Board received two comments stating that the rules should require that the health care professional be able to perform endotracheal intubation. This is required for ACLS certification. The Subcommittee agreed that it is unnecessary to add this requirement because in order for a health care professional or physician to be ALS certified, the health care professional or physician is required to know how to do this.

R4-16-706(A): The Board received two comments stating that the rules should require the equipment needed to carry out ACLS and PALS. The Subcommittee agreed no changes will be made to this rule as a result of this comment due to rule R4-16-703(A)(1) which requires a physician to ensure that the office-based surgery can be safely performed with the equipment at the physician's office.

R4-16-707: The Board received two comments stating that the rules should prohibit the use of propofol, diprivan, and inhalation agents except nitrous oxide or add a rule that requires equipment and medication necessary for supporting and circulation is available until the effects of the drug have dissipated or the patient is transferred to a medical facility before the physician performs the office-based surgery. The Subcommittee was in agreement that it would not be wise to provide a list of specific drugs that are authorized or prohibited because the list may be incomplete and would only apply to the listed drugs and the rules would constantly be amended as new drugs are made available. The Subcommittee agreed that since the rules prohibit general anesthesia, any drug or agent that is usually exclusively for general anesthesia will be prohibited.

R4-16-707(B): The Board received one comment stating that subsection (B) should be deleted because malignant hyperthermia can only occur during the use of a general anesthetic. The Subcommittee was in agreement with this comment and that these rules prohibit the use of general anesthesia. Dr. Lee noted that there rare occasions when other agents, such as Ketamine, could cause hyperthermia. The Subcommittee agreed this requirement should be changed to "When performing office-based surgery, a physician shall not use any drug or agent that may trigger malignant hyperthermia."

The meeting adjourned at 6:06pm

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Timothy C. Miller, J.D., Executive Director